

Instructions For Use

Therapy™ Cool Path™ Ablation Catheter

CAUTION:

- United States law restricts this device to sale by or on order of a physician.
- Do not attempt to use the device before completely reading and understanding the instructions for use.

DESCRIPTION:

The Therapy™ Cool Path™ Ablation Catheter is a sterile, single use 7F catheter that is constructed of thermoplastic elastomer material and four noble metal electrodes. This catheter has a through-lumen connected to open conduits at the 4mm tip electrode for heparinized saline irrigation during the ablation procedure. The tip curvature may be manipulated by the thumb control mechanism located in the handle at the proximal end of the catheter. The catheter is available in four distal curve configurations (M, L, FL and XL). The curve is indicated on the catheter label.

The catheter connects to the IBI-1500T9 RF Generator via a 1641 connecting cable. Refer to the Operator's Manual packaged with the generator for a description of the generator operations and related accessories including compatible infusion pump.

INDICATIONS FOR USE:

The Therapy™ Cool Path™ Ablation Catheter is intended for use with a compatible external infusion pump and the IBI 1500T9 Radiofrequency (RF) Generator at a maximum of 50 watts. The catheter is intended for creating endocardial lesions during cardiac ablation procedures (mapping, stimulation and ablation) for the treatment of typical atrial flutter.

CONTRAINDICATIONS:

The Therapy™ Cool Path™ ablation catheter is contraindicated for:

- Patients with active systemic infection;
- If the patient has intracardiac mural thrombus or has had a ventriculotomy or atriotomy within the preceding four week.

WARNINGS:

- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency catheter ablation in a fully equipped electrophysiology laboratory.
- The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data.
- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for this use of the device in pregnant women. The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in prepubescent children.
- Pacemakers and implantable cardioverter/defibrillators can adversely be affected by RF signals. It is important to: a) have temporary external sources of pacing and defibrillation available during ablation, b) deactivate ICD's as they could discharge and injure the patient or be damaged by the ablation

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procedure, c) exercise extreme caution during ablation when in close proximity to permanent pacing or defibrillation leads, and d) perform complete implantable device system analysis on all patients after ablation.

- The long-term risks of RF ablation lesions have not been established, particularly with respect to lesions placed in proximity to the specialized conduction system.
- Ablation within and in close proximity to the coronary arterial vasculature has been associated with myocardial infarction and death.
- In accordance with your hospital's protocol, monitor the patient's fluid balance throughout the procedure to avoid fluid overload.
- Always verify that the tubing and catheter have been properly cleared of air prior to inserting the catheter into the vasculature since entrapped air can cause potential injury or fatality.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.
- Do not use force to advance or withdraw catheter when resistance is encountered.
- When using an electrophysiology (EP) recording system, the equipment must be front-end isolated, or have an isolated patient cable.
- This device is intended for one time use only. Do not reprocess or reuse. Reuse can cause device failure, patient injury and /or the communication of infectious disease(s) from one patient to another.

PRECAUTIONS:

- If the infusion pump alarm sounds, RF energy will be terminated. Communication and fluid flow must be evaluated. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. Remove the catheter from the patient and inspect the catheter and the electrodes. If necessary, clean the electrodes with a sterile saline saturated gauze pad. Ensure that the irrigation ports are patent.
- The catheter impedance display of the cardiac ablation generator should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted that does not exceed the preset limit, power delivery **MUST** be manually discontinued. Clinically assess the situation. If necessary, the catheter should be removed from the patient and the distal tip of the catheter cleaned to eliminate any coagulum. Make sure fluid flows from the irrigations ports before re-inserting into the patient.
- Catheter advancement must be performed under fluoroscopic guidance in conjunction with internal electrograms and impedance monitoring to minimize the risk of cardiac damage, perforation or tamponade.
- Always straighten the catheter before insertion or withdrawal by completely retracting the thumb control knob bringing the catheter to its neutral (straight) position.
- Always maintain constant irrigation to prevent coagulation within and around electrodes.
- Do not use if catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve and/or if any of the irrigation ports are blocked.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Care should be taken when ablating near electrically vulnerable, thin-walled or other arterial structures.

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- Adequate filtering of mapping systems must be used to allow continuous monitoring of the surface or intracardiac electrocardiograms during radiofrequency power applications. Monitoring systems incorporating high frequency current-limiting devices are recommended.
- Needle monitoring electrodes are not recommended.
- Do not immerse the proximal handle or cable connectors in fluids; electrical performance could be affected.
- Position connecting cables such that contact with the patient and other electrical leads is avoided.
- If irrigation flow is interrupted, immediately inspect and reflush the catheter outside of the patient. Reestablish irrigation flow prior to placing catheter in the body.
- Do not attempt ablation without using an irrigation pump.
- Do not twist or pull at distal electrode. Excessive force may loosen the electrode from the catheter shaft.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- Do not expose the catheter to organic solvents, such as alcohol.

Potential Adverse Events

Potential adverse events that maybe associated with catheterization and/or cardiac ablation include:

- | | |
|--|---|
| • Abnormal vision | • Local hematomas/ecchymosis |
| • Adult Respiratory Distress Syndrome (ARDS) | • Myocardial infarction |
| • Air embolism | • Neck/pain/groin pain |
| • Anaphylaxis | • Obstruction or perforation or damage to the vascular system |
| • Anemia | • Palpitations |
| • Allergic reaction (anesthesia) | • Pericardial effusion |
| • Arrhythmias | • Pericarditis |
| • AV fistula | • Phrenic nerve damage |
| • Cardiac perforation/tamponade | • Pleural effusion |
| • Cardiac thromboembolism | • Pneumonia |
| • Cerebrovascular accident (CVA) | • Pneumothorax |
| • Chest pain/discomfort | • Pseudoaneurysm |
| • Complete heart block | • Pulmonary edema |
| • Component damage to ICD or implantable pacemaker | • Pulmonary embolism |
| • Congestive heart failure/exacerbation | • Radiation injury |
| • Coronary artery spasm | • Respiratory Depression |
| • Death | • Seizure |
| • Dislodgement of implantable cardioverter defibrillator or permanent pacing leads | • Skin burns |
| • Dizziness | • Syncope/near syncope |
| • Endocarditis | • Temporary complete heart block |
| • Esophageal injury (fistula) | • Thrombi |
| • Exacerbation of pre-existing atrial fibrillation | • Thromboembolism |
| • Expressive aphasia | • Transient ischemic attack (TIA) |
| • Heart Failure | • Unintended (in)complete AV, sinus node or other heart block or damage |
| • Hemothorax | • Valvular damage/insufficiency |

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|---|--|
| <ul style="list-style-type: none"> • Hypoxia/shortness of breath • Increased phosphokinase level • Infections/sepsis • Laceration | <ul style="list-style-type: none"> • Vascular bleeding • Vasovagal reactions • Ventricular tachycardia • Worsening chronic obstructive pulmonary disease |
|---|--|

SUMMARY OF CLINICAL STUDIES:

Objectives

A prospective, randomized multicenter study of RF ablation was conducted to demonstrate the Safety and Effectiveness of the Therapy™ Cool Path™ Ablation Catheter used in conjunction with the IBI 1500T9 RF Generator.

Study Design

The study was a prospective, randomized, non-blinded, multi-center controlled clinical study of patients requiring treatment for typical atrial flutter. The study was designed to demonstrate that safety and effectiveness of the Cool Path device was equivalent (not inferior) to that of a control device (i.e., legally marketed ablation catheters approved for the treatment of typical atrial flutter).

All patients were treated with radiofrequency ablation. Two-thirds of the patients were treated with the investigational device and one-third of the patients were treated with an FDA-approved device.

Clinical Endpoints

The primary safety endpoint was based upon serious adverse cardiac events occurring within 7 days of the index procedure ("Major Complications").

The primary effectiveness endpoint was acute procedural success defined as the creation of bi-directional conduction block and non-inducibility of typical atrial flutter at least 30 minutes following therapeutic intervention using only the randomized investigational or control catheter.

The secondary effectiveness endpoint was chronic clinical effectiveness defined as a lack of atrial flutter recurrences at three months follow-up.

Subjects Studied

| Status | Number of Investigational Arm Subjects | Number of Control Arm Subjects |
|--|--|--------------------------------|
| Screened | 326 | |
| Discontinued Prior to Randomization | 8 | |
| Randomized | 210 | 108 |
| Discontinued After Randomization, but Prior to Ablation: | 36 | 18 |
| Non-protocol arrhythmia | 22 | 16 |
| Other screen failure | | 1 |
| Withdrew consent | 3 | 1 |
| Physician discretion | 10 | |
| Equipment not available | 1 | |

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| Status | Number of Investigational Arm Subjects | Number of Control Arm Subjects |
|---------------------------------------|--|--------------------------------|
| Treated | 174 | 90 |
| Acute Failures | 13 | 3 |
| Acute Success | 161 | 87 |
| Death, post-ablation | 3 | |
| Lost to Follow-up | 9 | 6 |
| Chronic (3 month) follow-up available | 149 | 81 |
| Chronic Failure | 5 | 2 |
| Chronic Success | 144 | 79 |

Demographics

A total of 264 patients (174 Cool Path™, 90 Control) were treated at twenty-two (22) participating investigational sites. In 173 (of 174) investigational arm subjects, at least one attempt was made to deliver RF energy with the Study Device. One (1) subject was treated with a legally marketed non-study device. At least 1 attempt was made to deliver RF energy for the 90 control subjects. Of these 90 subjects, 82 were treated with a non-irrigated system while 8 were treated with an open irrigated system.

Of 174 patients randomized to be treated with the investigational device, 81.0% were male (141/174) with a mean age of 67.7 years and an average weight of 204 pounds. Of 90 patients randomized to be treated with the control device, 80.0% were male (72/90) with a mean age of 66.1 years and an average weight of 204 pounds. There was no significant difference between the treatment groups with respect to age, gender or weight.

Cardiac history (medical and surgical) is summarized below. Coronary artery disease (CAD) was present in 44.8% of investigational group subjects and 33.3% of control group subjects. Atrial fibrillation was present in nearly half of the subjects (48.9% investigational group, 44.4% control group). Prior coronary artery interventions were reported in 31.6% of investigational group subjects and 23.3% of control group subjects. Pacemaker or ICD Implants were present in 16.1% of investigational group subjects and 10.0% of control group subjects. There were no significant differences between the groups with respect to cardiac history, with the exception of CAD which occurred at a higher rate in the investigational group.

Procedural Data

A comparison of procedural parameters is provided in Table 1. Differences between the investigational and control groups were statistically significant for procedure time, power per application, temperature, fluoroscopy time, impedance and total fluid administered. This disparity was expected due to restrictions on the investigational device dictated by the protocol.

Per protocol, the maximum duration per application was 60 seconds for the investigational group. For the control group, there was no such restriction and durations as high as 390 seconds were applied. The limitation in duration is the primary reason for the greater number of RF applications which, in turn, led to increased procedure times for the investigational device.

Differences in procedural parameters such as temperature, power, impedance and total fluid are related to the operation of the open irrigation system used in the investigational group, compared to non-irrigated systems used to treat the 82 patients in the control group. Lower power and temperature as well as higher impedance reported in the investigational group are consistent with current literature results comparing irrigated versus non-irrigated systems.

Comparisons of Procedural Parameters

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| Measure | Investigational Group (n=174) | Control Group ¹ (n=90) |
|--|--|---|
| # OF APPLICATIONS PER PROCEDURE | 23.1 ± 16.1 (n=173) | 11.8 ± 9.3 (n=90) |
| RF TIME (Min.) PER PROCEDURE | 20.0 ± 14.2 (n=173) | 14.5 ± 10.5 (n=90) |
| FLUOROSCOPY TIME (Min.) PER PROCEDURE | 31.4 ± 24.5 (n=173) | 21.0 ± 19.6 (n=89) |
| PROCEDURE TIME (Min.) PER PATIENT | 133.7 ± 69.0 (n=170) | 96.5 ± 39.4 (n=90) |
| RF TIME (Sec.) PER APPLICATION | 52.2 ± 15.3 (n=3967) | 74.3 ± 48.5 (n=1057) |
| ENTRANCE SKIN EXPOSURE DOSE (Gy) PER PATIENT | $1.2 \times 10^{-2} \pm 2.0 \times 10^{-2}$ (n=165) | $8.2 \times 10^{-3} \pm 1.2 \times 10^{-2}$ (n=85) |
| TEMPERATURE (°C) PER APPLICATION | 37.3 ± 3.7 (n=3961) | 50.6 ± 8.4 (n=1043) |
| POWER (Watts) PER APPLICATION | 29.8 ± 7.5 (n=3962) | 43.9 ± 18.9 (n=1051) |
| IMPEDANCE (Ohms) PER APPLICATION | 94.3 ± 16.2 (n=3962) | 90.7 ± 40.7 (n=1049) |
| TOTAL FLUID ADMINISTERED (ml) | 1021.6 ± 561.8 (n=172) | 529.9 ± 389.9 (n=83) |

¹ Includes both irrigated (8) and non-irrigated (82) catheters

Results

Effectiveness:

Of the 264 treated subjects, there were 248 acute successes (161 investigational group, 87 control group) and sixteen (16) acute failures (13 investigational group, 3 control group). The acute procedural success rate was 92.53% (161/174) for the investigational group versus 96.67% for the control group (87/90). The upper 95% confidence limit (UCL) for the difference between treatment groups was 8.66%. The UCL was less than the prespecified non-inferiority margin of 10%. Thus, the pivotal study demonstrates that the Therapy™ Cool Path™ Catheter System is equivalent (non-inferior) to currently marketed devices with respect to effectiveness for its intended use.

Secondary Effectiveness Endpoint:

Of the 161 subjects in the investigational group that had acute procedural success, there were 149 subjects that were seen at the three months follow-up. There were 9 subjects lost to follow up and three subjects in this group died prior to the three month follow up. There were 5 subjects with recurrence of typical atrial flutter. 144/149 subjects (96.6%) were documented to have chronic success. 117/149 subjects (78.5%) were free from recurrence and anti-arrhythmic drug changes.

Of the 87 subjects in the control group that had acute procedural success, there were 81 subjects that were seen at the three months follow-up. There were 3 subjects lost to follow up, 1 subject failed to comply, 1 subject withdrew and 1 subject not included from the data due to treatment with a non-protocol catheter. There were 2 subjects with a recurrence of typical atrial flutter. 79/81 subjects (97.5%) were documented to have chronic success. 69/81 subjects (85.2%) were free from recurrence and anti-arrhythmic drug changes.

Safety:

Of the 264 treated subjects, there were twenty-two (22) major complications (14 investigational, 8 control) in twenty (20) treated subjects (12 investigational, 8 control). "Major Complications" include

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all serious, cardiac adverse events within seven (7) days of the index procedure. No unanticipated adverse device effects were reported in either group.

Major Complications (Investigational Group)

| No of Subjects | Event | Days Post-ablation |
|----------------|--|--------------------|
| 1 | RECURRENT AFIB, TX REQ | 2 |
| 1 | RECURRENT AFIB, TX REQ | 6 |
| 1 | CHEST PAIN, NON-ISCHEMIC, HOSP REQ | 1 |
| 1 | AFIB, TX REQ | 7 |
| 1 | AFIB, HOSP EXTENDED | 1 |
| 1 | CHEST PAIN, HOSP REQ | 2 |
| 1 | AFIB, TX REQ | 2 |
| 1 | PULMONARY EMBOLISM | 7 |
| 1 | CHEST PAIN, UNK ETIOLOGY, HOSP OBSERVATION | 1 |
| 1 | RECURRENT AFIB, TX REQ | 1 |
| | BRADYCARDIA, PACEMAKER REQ | 7 |
| 1 | AFIB, TX REQ | 1 |
| | BRADYCARDIA, PACEMAKER REQ | 7 |
| 1 | HEART BLOCK PACEMAKER REQ | 0 |

Major Complications (Control Group)

| No of Subjects | Event | Days Post-ablation |
|----------------|------------------------------------|--------------------|
| 1 | RECURRENT AFIB, HOSP REQ | 0 |
| 1 | ACUTE PERICARDITIS | 1 |
| 1 | HYPOTENSION, TX REQ | 0 |
| 1 | MI (NON-STE) | 2 |
| 1 | INDUCED ATRIAL TACHYCARDIA TX W/RX | 0 |
| 1 | WORSENING CHF, HOSP EXTENDED | 0 |
| 1 | CAD, SURGERY REQ | 0 |
| 1 | PULMONARY CONGESTION | 0 |

Three (3) deaths were reported among 174 subjects treated with the investigational device as described below. No deaths were reported in the control group.

- One subject was an 85 year old female with a history of atrial fibrillation (AFIB), coronary artery disease, pacemaker insertion (2004) and congestive heart failure. The ablation procedure was uneventful resulting acute success. After ablation was complete, a non target arrhythmia was still present (right atrial posterior wall "scar" flutter). The device performed as expected. The patient was hospitalized 44 days following the procedure and treated for CHF. The patient remained in

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the hospital with continued respiratory distress that deteriorated into cardio/pulmonary arrest and the patient died at 67 days following the procedure.

- The second subject was a 48 year old male with a history of CHF, and non-ischemic cardiomyopathy. The procedure for the study arrhythmia was performed without event resulting in acute success. After RF ablation was complete, a transient non-sustained atrial flutter was present. The device performed as expected. Thirty-three (33) days following the ablation procedure, the patient suddenly collapsed at work and was pronounced dead on arrival at a local hospital from an acute coronary event.
- The third subject was a 65 year old male with a history of hypertension and Crohn's disease. The procedure for the study arrhythmia was performed without event resulting in acute success. Forty five days (45) following the procedure, the patient was admitted to the hospital with pancytopenia and was diagnosed of lymphoma. The patient was treated with chemotherapy and died nineteen days (19) later secondary to an infection related to the pancytopenia.

The rate of major complications was 6.90% (12/174) for the investigational group versus 8.89% for the control group (8/90). The UCL for the difference between treatment groups was 3.87%. The UCL was less than the prespecified non-inferiority margin of 10%. Thus, the pivotal study demonstrates that the Therapy™ Cool Path™ Catheter System is equivalent (non-inferior) to currently marketed devices with respect to safety for its intended use.

PATIENT SELECTION AND TREATMENT RECOMMENDATIONS:

The patient should be prepared for the ablation procedure in accordance with standard clinical practice, for example:

- A baseline electrophysiological study documenting the presence of the arrhythmia,
- Discontinuation of antiarrhythmic drugs prior to the ablation procedure, and
- Anticoagulation therapy such as warfarin.

The safety and effectiveness of the Therapy™ Cool Path™ Ablation Catheter has not been studied in asymptomatic or pregnant patients.

DIRECTIONS:

1. Verify the IBI-1500T9 generator and related accessories are set up (except the 1641 cable) per the diagram in the RF generator Operator's Manual. Use care to isolate any unused connector pins of the 1804-S electrogram cable. This will reduce the chances of developing accidental current pathways to the heart.
2. Inspect the catheter package prior to use. Do not use if the package is open, damaged or expired.
3. Remove the catheter from its package. Inspect the electrodes and catheter carefully for integrity and overall condition.
4. Connect a sterile luer lock syringe filled with saline mix to the luer connection of the catheter. Push the contents of the syringe into the catheter to confirm all 6 irrigation ports are open.
5. Connect the catheter to the irrigation system using standard luer fittings.
6. Make sure to purge the tubing and catheter of air bubbles. Flush the catheter using a high flow pump setting. Add heparin to the saline infusion medium according to the patient's anticoagulant condition.
7. Connect the 1641 cable to the Therapy™ Cool Path™ catheter. Observe connector polarity; do not force connectors or pin damage can occur. Then connect the 1641 cable to the socket labeled ISOLATED PATIENT CONNECTOR on the generator front panel.
8. Power ON the generator and initialize the pump. Refer to the Operational Sequence Section of the RF generator Operator's Manual for a complete description of generator and pump set-up and communication between the two instruments.

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9. Prior to entering ablation parameters in the generator, ensure the indifferent electrode is appropriately placed on the patient's body.
10. Set the initial power level at 20 watts.
11. Set the initial temperature at 45°C. **NOTE:** Temperature represents the tip electrode temperature only and does not reflect tissue temperature.
12. Set the target duration time. The maximum duration time for each ablation shall be 60 seconds.
13. Make sure the catheter is in the neutral (straight) position before insertion. An 8F minimum introducer sheath may be used to aid in insertion. To avoid occlusion of the irrigation conduits, **THE CATHETER MUST BE CONTINUOUSLY IRRIGATED WHEN WITHIN THE VASCULATURE.** Irrigation should only be stopped after removal of the catheter from the body.
14. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy.
15. To adjust the curve of the distal tip, push or pull the thumb control located on the handle.
16. The pump flow rates and RF generator settings are as follows:

Equipment Parameters

| Pump Settings | | Basal Rate | During Ablation |
|---------------|--|------------|-----------------|
| Flow Rate | | 120 ml/hr | 800 ml/hr |

| RF Generator Settings | | Initial Setting | Maximum Setting |
|-----------------------|--|-----------------|-----------------|
| Power | | 20 Watts | 50 Watts |
| Temperature | | 45°C | 50°C |
| Maximum Duration | | 60 seconds | 60 seconds |

17. Press the START key on the generator to begin RF therapy (ablation).
18. After 15 seconds at a power setting, power may be increased in 5 watt increments as needed to create an effective lesion. Intracardiac electrogram **MUST** be assessed prior to changing power setting.
19. If the preset power output is not achieved at the initial temperature of 45 °C, it is permissible to increase the temperature setting to a maximum of 50 °C. Again, intracardiac electrogram **MUST** be assessed prior to changing temperature settings.
20. At the end of each ablation period, after 3 seconds, the pump will automatically return to the basal flow rate.
21. When the procedure is finished, make sure to pull the thumb control downward completely to bring the catheter to its neutral position (straight) before removing the catheter from the patient.

CONNECTION TO OTHER EQUIPMENT:

This device may be connected to a commercially available EP recording system and/or a compatible IBI radio frequency generator using a connection cable with connector in the pin configuration corresponding to this catheter. The use of cables with shrouded pins is recommended and is required in some countries such as the United States. Such equipment must be "patient isolated", or have an isolated patient cable. Current leakage from the connected EP recording system or RF generator must not exceed 10 micro amps for intracardiac electrodes.

PACKAGING AND SHELF-LIFE:

The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the products remain in the unopened inner package until time of use. Contents are sterile if the inner package is unopened.

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and undamaged. Do not resterilize. The expiration date is marked on the outside of the package. The product should be stored in a cool, dry location.

WARRANTY:

Irvine Biomedical, Inc. (IBI) warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "Expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products are set forth in the related "Instructions for Use" that accompany each product. IBI disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. IBI's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. IBI disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. IBI neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete IBI warranty policy available from IBI (1-949-851-3053) or on the back of an IBI invoice.